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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,684	04/19/2001	Franklin Okumu	10466/18	1800

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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60611

EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1653	8

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/839,684	Applicant(s) OKUMU, FRANKLIN	
	Examiner Jeffrey E. Russel	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The drawings are objected to because the writing in Figures 2-9, including the axis labels, is illegible. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The abstract of the disclosure is objected to because it is insufficiently detailed. More details concerning the components which are present in the composition are necessary. Correction is required. See MPEP § 608.01(b).

3. The claim for priority under 35 U.S.C. 119(e) inserted at page 1 of the specification by the preliminary amendment filed April 19, 2001 is objected to because of the use of non-standard claim language. The phrase "is based on" in the claim for priority should be changed to "claims the benefit of" (see MPEP 201.11 under "Reference To First Application") so that the claim for priority is clear. Correction is required.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not

only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 1 and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 0 216 485. The European Patent Application '485 teaches compositions comprising a complex of a growth hormone and a metal, preferably zinc, in combination with a thickened oil vehicle comprising mineral oil or vegetable oil, and optionally in combination with adjuvants or excipients which further extend the release rate of the metal-complexed growth hormone. Preferred oil vehicles are mixtures of peanut oil and aluminum monostearate, and mixtures of soybean oil and beeswax. The molar ratio of zinc to growth hormone is at least 1:1, preferably at least 2:1. The compositions are injected or introduced into an animal as an implant. See, e.g., page 2, lines 20-23; page 3, lines 14-17; and page 3, line 24 - page 4, line 22. The oil and the adjuvants or excipients of the European Patent Application '485 correspond to Applicant's non-polymeric, non-water soluble liquid material. In view of the similarity in composition, use, method steps, and extended release rate between the compositions of the European Patent Application '485 and Applicant's claimed compositions, the oil, adjuvants, and/or excipients are deemed inherently to have the same viscosity and crystallization properties claimed by Applicant, and the compositions of the European Patent Application '485 are deemed to have the same release rates claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the European Patent Application '485 and Applicant's claimed invention to shift the burden to Applicant to provide evidence that the claimed invention is unobviously different than that of the European Patent Application '485.

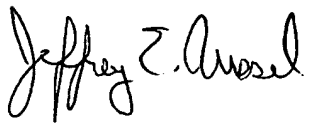
6. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 0 216 485 as applied against claims 1 and 26-30 above, and further in view of Tipton et al (U.S. Patent No. 5,747,058). The European Patent Application '485 teaches the use of biocompatible thickened oil vehicles in general (see, e.g., page 3, lines 29-32, and claim 10), but does not teach Applicant's particularly claimed carrier material comprising sucrose acetate isobutyrate and a solvent. Tipton et al disclose high viscosity liquid controlled delivery systems comprising a component (HVLCM) that has a viscosity of at least 5,000 cP at 37°C and that does not crystallize neat under ambient or physiological conditions. A preferred component is sucrose acetate isobutyrate (SAIB). The delivery systems can include solvents such as ethanol, propylene carbonate, and benzyl alcohol, which lower the viscosity of the delivery system, e.g. to less than 1000 cP or less than 200 cP, for purposes of administration and which then dissipate or diffuse, leaving a highly viscous implant. Ratios of SAIB:solvent of 60:40 and of 70:30 are exemplified. By selection of the HVLCM and the solvent, a wide variety of pre- and post-administration composition viscosities can be achieved. The delivery systems can be used for the controlled release delivery of substances such as natural and synthetic bioactive peptides and proteins, including growth factors. The substances to be delivered can preferably be present in amounts ranging from about 2 % to about 10% by weight. See, e.g., the Abstract; column 2, lines 47-67; column 8, lines 16-25 and 41-49; and column 14, lines 1-18. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the delivery system of Tipton et al as the biocompatible thickened oil vehicles of the European Patent Application '485 because the European Patent Application '485 is not limited to the use of any particular biocompatible thickened oil vehicle, because the delivery system of Tipton et al is

disclosed to be useful in delivering the same types of biologically active substances, i.e. proteins including growth factors, which are disclosed by the European Patent Application '485, and because use of the delivery system of Tipton et al as the biocompatible thickened oil vehicle of the European Patent Application '485 would have the advantage of providing simple controlled delivery systems which are easily formulated and which provide different pre- and post-administration viscosities for ease of administration (see, e.g., column 2, lines 30-67). Neither the European Patent Application '485 nor Tipton et al teach the exact release rates recited in instant claims 27-30, 32-35, and 37-40. However, the European Patent Application '485 does teach that use of the metal complexes of growth hormone allows a slower release rate upon injection than does the free form of growth hormone (see page 2, lines 7-10), and Tipton et al disclose that release rates can be chosen and optimized by appropriate choice of additives (see column 3, lines 30-44, and column 9, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to adjust the composition of the delivery system in order to optimize the release rates of the European Patent Application '485 as modified above by Tipton et al because the European Patent Application '485 discloses the desirability of a slower release rate upon injection and because Tipton et al disclose that release rate is a result-effective variable and therefore one of ordinary skill in the art would be motivated to optimize such a variable.

7. Mitchell (U.S. Patent No. 5,411,951) is cited as art of interest, teaching prolonged release compositions comprising metal complexes of polypeptides such as somatotropin in combination with an oil and an antihydration agent, and being essentially duplicative of the references applied above.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

September 25, 2002